



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/821,025	03/19/97	BIJL	246152006900

SHMUEL LIVNAT
MORRISON AND FOERSTER
2000 PENNSYLVANIA AVENUE NW
WASHINGTON DC 20006-1888

HM12/0123

EXAMINER

MARX, I

ART UNIT PAPER NUMBER

1651

DATE MAILED: 01/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Advisory Action

Application No.

08/821,025

Applicant(s)

Bijl et al.

Examiner

Irene Marx

Group Art Unit

1651



THE PERIOD FOR RESPONSE: [check only a) or b)]

- a) ☐ expires _____ months from the mailing date of the final rejection.
- b) ☐ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☒ Appellant's Brief is due two months from the date of the Notice of Appeal filed on Jan 8, 2001 (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on Jan 8, 2001 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

- ☒ The proposed amendment(s):

☒ will be entered upon filing of a Notice of Appeal and an Appeal Brief.

☐ will not be entered because:

- ☐ they raise new issues that would require further consideration and/or search. (See note below).
- ☐ they raise the issue of new matter. (See note below).
- ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

- ☐ Applicant's response has overcome the following rejection(s): _____
- _____

- ☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

- ☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:

see attachment

- ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

- ☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: none

Claims objected to: none

Claims rejected: 27-29, 31, 33 and 41-54. Claims 1-26 and 34-36 are withdrawn from consideration.

- ☐ The proposed drawing correction filed on _____ ☐ has ☐ has not been approved by the Examiner.

- ☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

- ☐ Other

IRENE MARX
PRIMARY EXAMINER
ART UNIT 1651

The amendment filed 8/8/01 is acknowledged. Claims 27-29, 31, 33 and 41-54 are being considered on the merits.

Claims 1-26 and 34-36 are withdrawn from consideration as directed to a non-elected invention.

Applicant's arguments and Bijl declaration have been fully considered but they are not deemed to be persuasive. It is applicants' position that a granulate may be prepared while leaving the cells "intact". Yet, the term "intact", from the Webster dictionary definition is:

1 : untouched especially by anything that harms or diminishes : ENTIRE, UNINJURED.
2 : of a living body or its parts : having no relevant component removed destroyed: a : physically virginal; b : not castrated. Synonym see PERFECT.

Applicants also argue that intact means that the cell wall is not disrupted. However, this meaning is repugnant to the art recognized meaning and cannot be accepted.

Therefore, the new matter and indefiniteness rejections are deemed proper.

Regarding the art rejections, Applicant's arguments and the Bijl declaration have been fully considered but they are not deemed to be persuasive.

Applicants appear to wish to interpret the present claims as being directed to dried, dead material. However, these limitations are not found in the claims as written. Claim 27, for example, is directed to "a porous free-flowing granulate formed by extrusion consisting essentially of intact dead microorganisms or dead microbial cells". There is no indication that the material is "dried" or that absolutely all of the cells must be dead. In addition, claims 29 and 54 and claims dependent thereon are directed to a composition open to the inclusion of wet, live cells by virtue of the open language "comprising". Furthermore, the composition is claimed as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Moreover, as noted previously, the transitional phrase "consisting essentially of" does not exclude the inclusion of cells that are alive. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551 - 52, 190 USPQ 461, 463 (CCPA 1976)(emphasis in original)(Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). See also *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama - Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. v. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063 - 64 (Bd. Pat. App. & Inter. 1989)("Although 'consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps . . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by 'consisting essentially of' language.").

The touted advantages for the extraction of valuable products are noted. However, this is not relevant to the claims under examination, which are not directed to a process of extraction, but rather are directed to a microbial product. That the intended use of the invention is to extract products from the extruded material does not render patentably distinct a product which is the same or substantially similar to the products disclosed in the cited prior art. There is nothing in the prior art products that would prevent the extraction of vitamins or other useful products therefrom.

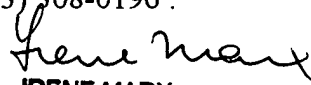
Regarding the touted advantages, it is also of interest to note that the written disclosure is directed to the recovery of specific products, i.e, PUFA containing oils, β -carotene, TAPS, and lovastatin from specific fungal or yeast species of *Mortierella*, *Cryptocodinium*, *Blakeslea*, *Pichia* and *Aspergillus*, which are known to produce these products. This is not the invention as claimed. In addition, it is not clear from the record whether or not the touted recovery advantages can be directly correlated to the nature of the material as claimed for any and all microbial extrudates or to the basic nature of the cells extracted.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


IRENE MARX
PRIMARY EXAMINER